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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/586,742	MARCHE ET AL.	
	Examiner	Art Unit	
	ZACHARIAH LUCAS	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-22* is/are pending in the application.

4a) Of the above claim(s) *14,15 and 19-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12,13,16-18 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/4/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 12-22 are pending in the application.

Election/Restrictions

2. Applicant's election with traverse of Group I in the reply filed on July 14, 2008 is acknowledged.

Applicant first asserts that there is no lack of unity in claim 16, thus it is inappropriate to require a species election in claim 17. The argument is not found persuasive. Lack of unity is found where the broadest claims in the application lack unity of invention. Such was shown in the restriction requirement.

Applicant next asserts that because claims 12-15 are drawn to composition claims, they cannot be limited to a certain pathology. While this may be true, the requirement for the species election is still appropriate for the method claims. The argument is therefore not found persuasive.

Applicant asserts that the Examiner has not shown that the alternatives in claim 12 fail to share "a similar nature" and thus has not established that the inventions are distinct. The argument appears to be based on the assertion that the Examiner has not shown that the reference anticipates the claim in view of the claim language requiring that the antibody inhibits the pro-inflammatory cascade referred to by the claim. The Applicant's arguments are not found persuasive. Contrary to Applicant's assertion that the disclosure of the use of the HTA125 antibody by Wang does not anticipate the invention, it is noted that claim 12 is drawn to a composition comprising the indicated antibody. As Wang discloses the antibody, the reference anticipates the claims (therefore breaking unity) regardless of whether the reference recognizes

any additional characteristics of the antibody. I.e. the claim merely identifies a functional characteristic that is inherent to the disclosed HTA125 antibody. Such identification is not sufficient to distinguish from the art that teaches the claimed composition.

The arguments are therefore not found persuasive. The requirement is still deemed proper and is therefore made FINAL.

3. Claims 14, 15, 19-21 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on July 14, 2008.

4. Claims 12, 13, 16-18, and 22 are under consideration.

Information Disclosure Statement

5. The information disclosure statement (IDS) submitted on January 4, 2007 is in compliance with the provisions of 37 CFR 1.97. However, pages 2-4 of the listing are not in compliance with 37 CFR 1.98(a)(1)(i) and (iii). These pages of the IDS have therefore not been considered.

References and 4-6 are in a foreign language accompanied by an English abstract. The references have therefore been considered to the extent of the English abstract.

Claim Objections

6. Claims 12 and 18 are objected to because of the following informalities: the claims identify various proteins and viruses by acronyms without first providing the full name of the protein or virus. Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 12, 13, and 16-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims are drawn to compositions capable of or methods for the purpose of inhibiting "the pro-inflammatory cascade induced by the activation of MSRV/HERV-W." However, the application indicates that MSRV is responsible for at least two distinct pro-inflammatory responses. See e.g., pages 1 and 3. Moreover, teachings in the art indicate that other HERV-W Env proteins are involved in other pro-inflammatory responses. See e.g., Antony et al., (J Immunol 179:1210-24- describing the involvement of an HERV-W env protein in a different pro-inflammatory response from those described in the present application as being associated with the MSRV envelope protein). As there are multiple pro-inflammatory responses, and thus cascades, induced by MSRV, it is not clear from the claims which cascade is meant by reference to "the pro-inflammatory cascade."

For the purposes of this action, the claims are therefore read as including any antibody that inhibits any pro-inflammatory responses induced by the indicated viral proteins.

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 12, 13, and 16-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for antibodies for the inhibition of a multiple sclerosis-associated retrovirus (MSRV) induced pro-inflammatory cascade induced by the MSRV Env protein and involving the toll-like receptor 4 protein and methods of using the antibodies for such inhibition, does not reasonably provide enablement for antibodies, or the use of antibodies, against the SU proteins of any MSRV/HERV-W viruses that inhibit any pro-inflammatory cascade induced by any HERV-W viruses. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In making a determination as to whether an application has met the requirements for enablement under 35 U.S.C. 112 ¶ 1, the courts have put forth a series of factors. See, In re Wands, 8 USPQ2d 1400, at 1404 (CAFC 1988); and Ex Parte Forman, 230 U.S.P.Q. 546 (BPAI 1986). The factors that may be considered include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the

claims. Id. While it is not essential that every factor be examined in detail, those factors deemed most relevant should be considered.

The claims are rejected on three grounds.

First, the claims are rejected as lacking adequate enabling support for antibodies that inhibit the pro-inflammatory responses induced by any HERV-W Env protein. This portion of the rejection has two parts. First, the application is not enabling for the use of anti-MSRV Env antibodies for the inhibition of pro-inflammatory responses by other HERV-W Env proteins, or for the inhibition of pro-inflammatory responses to the MSRV Env protein other than that associated with the TLR4 receptor. Secondly, the application is not enabling for the making and use of antibodies that inhibit pro-inflammatory responses by other HERV-W Env proteins.

The rejected claims are drawn to compositions comprising an antibody against MSRV/HERV-W Env-SU, which inhibit the proinflammatory cascade induced by the activation of MSRV/HERV-W. It is noted that the application indicates that the term MSRV/HERV-W refers broadly to any member of the HERV-W family. Page 1, lines 34-36. The claims are therefore drawn to antibodies and methods of using such wherein the pro-inflammatory cascade is induced by any of the HERV-W proteins, and is not limited to cascades induced by MSRV proteins. Moreover, as was indicated above, because the MSRV and HERV-W viruses induce multiple pro-inflammatory cascades, and as the claims do not specify that the responses are those involving the TLR4 protein receptor, the claims also include antibodies (and methods of using such) that inhibit any of the HERV-W induced pro-inflammatory cascades.

In support of the claimed invention, the application discloses three antibodies (those identified in claim 22) that inhibit the pro-inflammatory cascade induced by an apparent interaction with the MSRV Env protein and the TLR4 protein receptor. These antibodies are disclosed as specifically binding the MSRV Env protein. The application provides no disclosure of any other antibodies that inhibit any other pro-inflammatory response induced by MSRV Env, any other pro-inflammatory response induced by any HERV-W other than MSRV.

It is also noted that the application discloses that one antibody (not one of the three inhibitory antibodies) was cross reactive for MSRV and another HERV-W viral Env protein. See, pages 36 (lines 5-18) and 88, and Figure 24. However, the application does not disclose the binding epitope of that antibody, or identify the antibody as capable of inhibiting pro-inflammatory responses induced by any MSRV/HERV-W Env proteins. Thus, the application provides no basis on which to rest the assertion that the cross-reactivity of this antibody is indicative of cross-reactivity in the claimed anti-MSRV Env inflammation inhibiting antibodies. The application provides no evidence that the three disclosed inhibitory antibodies are also cross reactive.

The application does provide an alignment of the two HERV-W Env sequences against which the cross-reactive antibody was tested. Figure 23. However, as noted above, the application fails to disclose the epitope targeted by the antibody. Thus, the provided information does not permit those in the art to determine to what extent other anti-MRSV Env antibodies would share the cross-reactivity of this antibody.

Moreover, in the provided alignment, it is noted that two of the three epitopes targeted by the claimed antibodies are not conserved, and that at least one residue near (but outside of) the

third epitope also changes between the sequences. Teachings in the art indicate that single amino acid changes can alter the antigenicity of the protein. See e.g., Riffkin et al., Gene 167:279-83, abstract (indicating that a single amino acid change between two proteins determines the ability of such proteins to bind to an antibody). The art also indicates that amino acid substitutions outside of an antigenic site in a protein may affect that ability of the protein to react with antibodies targeting the protein. Abaza et al., J Prot Chem 11:433-44. Thus, the art indicates that there is uncertainty in the ability of mutant versions of proteins to interact with antibodies directed against the original protein. Moreover, other teachings in the art indicate that there is heterogeneity among the HERV-W sequences other than the two identified in the present application. See e.g., Kim et al. AIDS Res Hum Retrovir 17:643-48, at 644-45 (Table 1 and Figure 2). In view of this heterogeneity, and despite the cross-reactivity of the single undefined antibody referred to in Figure 24 of the application, the teachings in the art indicate that those in the art would not have expected cross-reactivity among all, if any, of the inhibitory antibodies within the scope of the claims.

Thus, the teachings in the art indicate that those in the art would not have expected that the three disclosed antibodies, which inhibit the TLR-4 associated pro-inflammatory responses of the MSRV Env protein, would also be able to inhibit the pro-inflammatory responses of other HERV-W Env proteins as they would not have expected the antibodies to be cross-reactive, or known, without undue experimentation, which antibodies would be able to inhibit inflammatory responses induced by other HERV-W proteins, or which such responses such antibodies would be capable of inhibiting.

As was indicated above, the claims are also rejected because the application is not enabling for the making and use of antibodies that inhibit pro-inflammatory responses by other HERV-W Env proteins. It was noted that the application provides no disclosure of any antibodies that inhibit any pro-inflammatory response induced by any HERV-W other than the MSRV Env protein. The lack of such showings is important not only in view of the uncertainty in the art as to the ability of known antibodies to bind other HERV-W Env sequences, but also because the art also indicates that different HERV-W proteins induce inflammation through different mechanisms. See e.g., Antony et al., AIDS Res Hum Retrovir, 23:1251-56, at pages 1251 and 1256 (indicating that the env proteins of MSRV and a different HERV-W Env protein mediate different inflammatory responses in different portions of human anatomy). By indicating that different HERV-W Env proteins induce different inflammatory responses, the teachings in the art suggest these different proteins interact with different proteins associated with inflammation pathways. In order to interact with different proteins, it would also appear that the different HERV-W Env proteins have different protein interaction domains. Thus, those in the art would not have expected the antibodies that inhibit one HERV-W protein from interacting with one protein, or that inhibits the pro-inflammatory activity of one HERV-W Env protein, to also inhibit such interaction or activity of another protein.

Further, because the art suggests the presence of such different interaction domains, and as neither the art, nor the application, teach antibodies that inhibits such other interactions, or regions or epitopes that may be targeted to achieve such inhibition, there is no data in the application providing any guidance towards such other antibodies.

In view of the breadth of the claims, the limited number of working examples, the limited teachings provided in the application and in the art, and the numerous sources of uncertainty with respect to the extent of the anti-inflammatory activity of the disclosed antibodies and as to what other antibodies may be used as specified by the claims, the claims are rejected as lacking adequate enabling support for compositions comprising any anti-MSRV/HERV-W Env antibody that inhibits a pro-inflammatory cascade induced by MSRV?HERV-W activation.

It is noted that an attempt to avoid this rejection through the amendment of the claim to read on the use of an anti-MRSV Env antibody would not be found persuasive. It is noted that page 1 of the application specifies that the term MSRV is treated as synonymous with MSRV/HERV-W. Thus, an amendment of the claim to refer to an anti-MSRV Env-SU antibody would not be effective in limiting the claimed antibodies to those that specifically bind the MSRV Env protein. The definition of MSRV provided in the application indicates that such antibodies would still include those that target any member of the MSRV/HERV-W family. Moreover, an amendment of the specification to change the definition of the term MSRV may be considered new matter to the application.

The second ground for rejection is that the application does not enable the use of antibodies against MSRV/HERV-W Env-SU antibodies that are capable of inhibiting any inflammatory response that is induced by MSRV/HERV-W activation generally.

As indicated above, the claims are drawn to compositions comprising an antibody against MSRV/HERV-W Env-SU, which inhibit the proinflammatory cascade induced by the activation of MSRV/HERV-W, and to methods of using such antibodies. The claims are not limited to the

use of the anti-MSRV/HERV-W Env antibodies to inhibit pro-inflammatory responses induced by the target Env proteins. Rather, the claims are drawn to the inhibition of any pro-inflammatory response induced by the activation of MRSV/HERV-W generally. Thus, the claims read on methods of inhibiting pro-inflammatory responses that may be induced by other MSRV/HERV-W proteins, such as the gag or pol proteins.

The support provided by the application has been described above. It is noted that the application nowhere indicate that the disclosed anti-Env antibodies would be capable of inhibiting pro-inflammatory responses induced by the activation of MSRV/HERV-W generally. Rather, the application uses an anti-MSRV Gag antibody as a negative control in several of the experiments. See e.g., page 58, lines 8-9. In using the anti-MSRV gag antibody as a control, the application is indicating that neither the Applicant, nor those in the art, would have expected the anti-Gag antibodies to have an effect on Env associated inflammation. The application therefore also indicates that those in the art would similarly not have expected that the anti-Env antibodies would inhibit responses induced by other MSRV/HERV-W proteins. Because those in the art would not have expected that the anti-Env antibodies would be capable of inhibiting responses induced by other MSRV/HERV-W proteins, and in view of the absence of any evidence that such antibodies are in fact so capable, the claims are rejected as lacking adequate enabling support for the use of the antibodies for the inhibition of any pro-inflammatory response induced by any activation of MSRV/HERV-W other than by expression of the Env protein.

The third ground of rejection applies to claim 16. This claim is drawn to a method of treating "a pathology associated with MSRV-HERV-W," comprising administering the

composition of claim 12 (i.e. the inflammation inhibiting anti-MSRV Env antibodies). The claim does not specify that the pathology is associated with the MSRV/HERV-W Env protein. Rather, the claim reads broadly on the treatment of any disorder associated with these endogenous viruses.

As was indicated above, the application lacks enabling support for the use of anti-MSRV/HERV-W Env antibodies for the treatment of inflammatory responses that may be induced by other MSRV/HERV-W elements. In addition, while the application suggests several disorders in which the MSRV Env protein may play a part, the application provides no teachings relating to what pathologies may be associated with other MSRV/HERV-W elements (such as the gag or pol proteins). In view of the lack of any guidance or teachings with respect to the identification of what other pathologies may be associated with MSRV/HERV-W, and the lack of any evidence that anti-inflammatory anti-MSRV/HERV-W Env antibodies would be capable of treating such other pathologies, the claim is rejected for exceeding the scope for which enabling support has been provided.

11. Claims 12, 13, 16-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. As indicated above, these claims are drawn to a genus of anti-MRSV/HERV-W Env-Su antibodies that inhibit a pro-inflammatory cascade induced by activation of MSRV/HERV-W.

The claims are rejected as lacking adequate support for any antibodies other than those that target the MSRV Env-Su protein (of SEQ ID NO: 3), and have the activity of inhibiting the Env induced pro-inflammatory response involving the TLR4 receptor.

The following quotation from section 2163 of the Manual of Patent Examination Procedure is a brief discussion of what is required in a specification to satisfy the 35 U.S.C. 112 written description requirement for a generic claim covering several distinct inventions:

> The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice..., reduction to drawings..., or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus... See Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406.
>
> A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

It is also noted that even the presence of multiple species with in a claimed genus does not necessarily demonstrate possession of the genus. See, In re Smyth, 178 U.S.P.Q. 279 at 284-85 (CCPA 1973) (stating "where there is unpredictability in the performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus or combination claimed at a later date in the prosecution of a patent application."); and University of California v. Eli Lilly and Co., 43 USPQ2d 1398, at 1405 (Fed Cir 1997)(citing Smyth for support). Thus, when a claim covers a genus of inventions, the specification must provide sufficient written description support for the entire scope of the genus. Support for a genus is generally found where the applicant has provided a number of examples sufficient so that one in the art would recognize from the specification the scope of what is being claimed, or provided a function and a structure

correlating with that function. Moreover, in situations where the operability of other species than those provided is uncertain, additional support is required over that which would be required where greater certainty is present.

The present claims lack adequate written description support for two reasons. First, there is inadequate descriptive support for antibodies that inhibit any MSRV/HERV-W pro-inflammatory response other than that induced by MSRV Env protein via the TLR4 receptor pathway. Second, there is inadequate descriptive support for any antibodies that inhibit any pro-inflammatory response induced by Env proteins from other members of HERV-W family.

As was indicated in the enablement rejection above, the present application discloses only three antibodies that target the MSRV Env protein, and inhibit the pro-inflammatory response of the protein. Each of these antibodies is indicated to specifically inhibit the TLR4 associated pro-inflammatory response against the protein. However, the application indicates that the MSRV protein itself induces at least two distinct pro-inflammatory responses. Moreover, the teachings in the art (see, Antony et al., AIDS Res Hum Retrovir, 23:1251-56, supra.) indicate that other HERV-W Env antigens also induce distinct pro-inflammatory responses from those of the MSRV Env protein.

Neither the teachings in the art, nor the teachings in the application, indicate that antibodies inhibiting one of the MSRV Env pro-inflammatory responses would also be capable of inhibiting the other such responses in at host. Nor do the teachings in the art or application provide any evidence that disclosed antibodies would be capable of inhibiting pro-inflammatory responses against other HERV-W Env proteins. Rather, as was described above, the teachings in the art and in the application indicate that there would be substantial uncertainty in the art a) as to

whether the disclosed antibodies inhibiting the TLR4 associated pro-inflammatory responses would also be capable of inhibiting the other pro-inflammatory responses induced by either the MSRV Env protein or the Env proteins of other HERV-W endogenous viruses, and b) as to the identity of the antibodies that inhibit the other pro-inflammatory responses by either the MSRV or HERV-W Env proteins. It is also noted that neither the application nor the art teach the regions of the MSRV or other HERV-W Env proteins that are responsible for the pro-inflammatory responses, or that are targeted by antibodies with the requisite inflammation inhibiting effect.

Thus, the application provides support for only anti-MSRV Env antibodies that inhibit the TLR4 associated pro-inflammatory effect induced by the MSRV Env protein. The application does not disclose any exemplary species of anti-MSRV/HERV-W Env antibodies that inhibit any other pro-inflammatory responses so as to provide descriptive support for the genus encompassing any of such antibodies. Nor does the application provide any more than a functional description of such other antibodies. I.e., the application does not disclose any non-functional characteristic that correlates with the required function (e.g., through the identification of a target epitope or region of the MSRV/HERV-W Env proteins bound by inflammation inhibiting antibodies).

In view of the lack of such disclosure, and the uncertainty in the art as to the identity and operability of such other antibodies, the claims are rejected as lacking adequate descriptive support for the claimed genus.

In avoiding this rejection, it is noted that page 1 of the application specifies that the term MSRV is treated as synonymous with MSRV/HERV-W. Thus, an amendment of the claim to

refer to an anti-MSRV Env-SU antibody would not overcome this portion of the rejection as the application indicates that such antibodies would include those that target any member of the MSRV/HERV-W family. Moreover, an amendment of the specification to change the definition of the term MSRV may be considered new matter to the application.

12. Claim 22 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The antibodies identified by the claim are required to practice the claimed invention. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit of cell lines producing the antibodies. See 37 CFR 1.802. One cannot practice the claimed invention without the antibodies. Therefore, access to them is required to practice the invention. The specification does not provide a repeatable method for readily identifying the antibodies without access to them and it does not appear to be readily available material.

Deposit of the material in a recognized deposit facility would satisfy the enablement requirements of 35 U.S.C. 112, because the strains would be readily available to the public to practice the invention claimed, see 37 CFR 1.801- 37 CFR 1.809.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

(a) during the pendency of this application, access to the invention will be afforded to one determined by the Commissioner to be entitled thereto;

(b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;

(d) a viability statement in accordance with the provisions of 37 CFR 1.807; and

(e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803 - 37 CFR 1.809 for additional explanation of these requirements.

Conclusion

13. No claims are allowed.

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. WO 01/31021 (of record in the January 2007 IDS). This reference suggests the use of antibodies targeting the SRV/HERV-W Env protein that inhibit the proteins superantigen activity. See e.g., claim 19 and pages 26-28. However, the reference does not actually disclose any such antibodies, or identify the regions of the HERV–W Env protein that may be targeted to inhibit the activity. Thus, while the reference may suggest to those of ordinary skill in the art those antibodies, and the method of use of such antibodies, as claimed the reference does not appear to provide sufficient information to anticipate or render obvious the presently claimed invention.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is (571)272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Zachariah Lucas/
Primary Examiner, Art Unit 1648